

Decisions taken in the 91st Meeting of the Genetic Engineering Approval Committee held on 14.1.2009.

The 91st meeting of the Genetically Engineering Approval Committee (GEAC) was held on 14.1.2009 in the Ministry of Environment and Forests under the Chairmanship of Shri B. S. Parsheera, Special Secretary and Chairman GEAC.

The deliberations of the GEAC in respect of Agenda Items 4 to 8 are as follows:

Agenda Item No 4: Policy Issues

4.1 Recommendations of the Sub-committee constituted by the Ministry to operationalize the 'event based approval mechanism' adopted by the GEAC in its meeting held on 2.4.2008.

4.1.1 The GEAC had constituted a Sub-committee under the chairmanship of Dr. P. L. Gautam, Deputy Director General (Crop Science), ICAR, to suggest suitable guidelines and to prepare a draft notification to operationalize the event based approval mechanism adopted by the GEAC in its meeting held on 2.4.2008. The Sub-committee recommended a decentralized system, whereby the responsibility of approving Bt cotton hybrids expressing approved events may be entrusted to the State Agriculture Universities and State Department of Agriculture.

4.1.2 The recommendations of the Sub-committee were discussed in the GEAC meeting held on 12.11.2008 wherein it was decided to request ICAR to take the responsibility of operationalizing the 'event based approval mechanism' in view of the vast experience and expertise available with ICAR under the existing AICCIP mechanisms.

4.1.3 The Committee took note of the comments received from DG, ICAR wherein it has been informed that "the new decentralized system of evaluating Bt cotton hybrids by the SAUs and State Departments of Agriculture would be more appropriate as (i) the states have experienced experts; (ii) they could ensure better and effective monitoring if the trials are conducted under the administrative control of the State Govts, and (iii) to obtain precise information on the performance of the hybrids in a systematic manner so that newer and better performing hybrids are identified for specific regions / states."

4.1.4 The Committee also considered views received from the GEAC members, some of the members of the Seed Industry and Dr P M Bhargava, the invitee. It was noted that opinion on the matter was divided. While the MoA /ICAR and some GEAC members and the Seed Industries were of the view that the new decentralized system of evaluating Bt cotton hybrids by the SAUs and State Departments of Agriculture would be more appropriate, others were of the view that the GEAC may consider constituting a 'Standing Committee' at the Central Government level for evaluation of Bt cotton hybrids expressing approved events under the event based approval mechanism.

4.1.5 After detailed deliberations, it was agreed that the current practice of hybrid by hybrid approval does not involve any biosafety issues and therefore may be treated at par with the conventional cotton hybrids. However, the Committee also agreed that it would be prudent to formally register the information on Bt cotton hybrids at the Central Government level. On the process of operationalising the 'event based approval mechanism, the following decisions were taken:

- The applicants (private/public sector organizations) who are interested in commercial cultivation of Bt cotton hybrids expressing approved events shall file applications along with affidavits to the 'Standing Committee' confirming/stating the following:
 - a) Confirmation of gene/ event through molecular characterization by the Licensor that the gene(s) which is being used is one of the approved events.

- b) Level of protein expression in green house and field trials
 - c) Morphological characters using DUS descriptors
 - d) Bio-efficacy data generated in laboratory conditions
 - e) Authorization / No Objection Certificate from technology provider in case of sub-licensee.
- The 'event based approval mechanism' shall be applicable for Bt cotton hybrids expressing four events namely; cry 1Ac (MON 531 event), *cry 1 Ac* and Cry 2 Ab (MON 15985 Event, (*cry 1 Ab + Cry Ac*) *GFM*' and *cry 1 Ac* (Event1). In respect of cry 1Ac (Dharwad) event developed by Central Institute of Cotton Research (CICR), Nagpur, it was decided that the new procedure would be applicable only after the event completes three seasons of commercial cultivation.
 - A 'Standing Committee' comprising of experts in the field of plant breeding, an entomologist, an agronomist and a plant pathologist would be constituted by the Chairman, GEAC. It was further agreed that the 'Standing Committee' would comprise of experts who are not members of the RCGM / GEAC. However, a representative from the GEAC/ RCGM could be included to ensure continuity and also to interface with the Committee and the GEAC / RCGM. The 'Standing Committee' would be serviced by the Department of Biotechnology. The terms of reference of the Committee would be as follows:
 - Evaluate the applications for commercial release of Bt cotton hybrids expressing approved events and verify that the affidavits are in order.
 - The Standing Committee shall identify 10% of the total applications received and send the samples to the referral laboratory at CICR, Nagpur for verification of the claims submitted along with the affidavit. Other laboratories including in the private sector having requisite capability will be identified for acting as referral laboratories for this purpose.
 - The Standing Committee shall maintain complete records of all the applications referred to it.
 - The Standing Committee will lay down procedure for identifying 10% of the applications for necessary verification.
 - Once an application has passed the scrutiny of the Standing Committee, the release of Bt cotton hybrids in the respective state may follow the same process as that for conventional cotton seeds.

4.1.6 During the deliberations, Director, CICR informed the Committee that CICR has been notified by the Ministry of Agriculture as a referral lab only for cry 1Ac (MON 531 event) and therefore, the subsequent gazette notification of the MoEF empowering all laboratories notified under the Seed Act also under EPA would be strictly applicable only for cry 1Ac (MON 531 event). The Committee requested the MoEF to take up the matter with the Ministry of Agriculture for issuance of necessary amendments expeditiously. It was also agreed that in addition to CICR, Nagpur, there is a need to identify NABL accredited laboratories for verification of Bt gene in cotton seeds.

Agenda Item No 5:

5.1 Presentation on field trials of Bt. Brinjal expressing Cry 1 Ac gene M/s. Mahyco, Mumbai and studies conducted under the supervision of Dr. Matura Rai , Director, IIVR, Varanasi.

5.1.1 M/s Mahyco has developed transgenic brinjal plants with cry 1Ac gene from *Bacillus thuringiensis* tolerant to the fruit and shoot borer, one of the major pests which attack the brinjal crop throughout its life cycle. This gene had been obtained as per the permit dated 16.3.2006 from the DBT. This gene was used to transform the proprietary brinjal line through Agro-bacterium –mediated

transformation. The gene was then transferred into other Mahyco brinjal proprietary lines through traditional backcrossing method.

5.1.2 The Member Secretary, GEAC briefed the Committee on the chronology of Bt brinjal developed by M/s Mahyco and the review process undertaken by the RCGM / GEAC / Expert Committee on Bt brinjal. It was noted that the GEAC in its meeting held on 8.8.2007 accorded permission to M/s Mahyco for large scale trials and seed production of Bt brinjal hybrids namely MHB-4 Bt, MHB 9 Bt, MHB 10 Bt, MHH 80 Bt , MHB-99 Bt, MHB-11 Bt and MHB -39 Bt containing cry 1 Ac gene based on the recommendations of the Expert Committee on Bt. brinjal constituted by the GEAC under the chairmanship of Dr. C. R. Babu, former Vice-Chancellor, Delhi University and recommendations of the MEC and the RCGM under the direct supervision of Director, Indian Institute of Vegetable Research (IIVR), Varanasi subject to certain conditions.

5.1.3 The representatives of the Ministry of Health and Family Welfare informed the Committee that their Ministry has received several reports on the adverse impacts of Bt brinjal on human health which needs to be looked into before a decision on commercial release of Bt brinjal is taken by the GEAC. It was clarified that the proposal of Bt brinjal was placed on the agenda with a view to review the findings of the LST and other related studies and not for taking a decision on commercial release of Bt brinjal. The Committee requested the representative of IIVR to make a presentation on the findings of the large scale trials. However, the presentation could not be completed as some of the members were of the view that the Bt brinjal data needs to be examined in light of the findings of the Austrian study and counter responses received on the issue.

5.1.4 After detailed deliberations, the Committee decided to set up a Sub-committee comprising of representatives from the Ministry of Health and Family Welfare, NIN, ICMR, CFTRI, CCMB, IIVR, NDRI, CFIE, MoEF DBT, TNAU and UAS Dharwad with the following terms of reference:

- to review the adequacy of the biosafety data on Bt brinjal
- to review the adequacy of the toxicity and allergenicity protocols
- to suggest further studies, if any, based on the review of the international practices in biosafety assessment and representations received by the GEAC.
- based on such reviews make suitable recommendations for consideration of the GEAC.

The Committee authorized the Chairman, GEAC to constitute the Sub-committee.

Agenda item No. 6: Consideration of Applications for MLRT/strip trials and experimental seed production of transgenic crops expressing new genes/events as recommended by the RCGM.

6.1. Permission to conduct confined field trials (Biosafety Research Trials I) on two Bt sorghum lines containing cry 1B gene NRCSCRY1B event 4 and NRCSCRY 1B event 19 during summer (Jan 2009-May 2009) along with non transgenic lines (M35-1) and natural resistance germplasm line (IS 2205) submitted by National Research Centre for Sorghum (NRCS), Hyderabad.

6.1.1 The Committee considered the request from M/s National Research Centre for Sorghum (NRCS), Hyderabad to conduct confined field trials (Biosafety Research Trials I) on two Bt sorghum lines containing cry 1B gene NRCSCRY1B event 4 and NRCSCRY 1B event 19 during summer (Jan 2009-May 2009) along with non transgenic lines (M35-1) and natural resistance germplasm line (IS 2205) resistant to stem borer. It was noted that the trials would be conducted within the institutional research farm at DOR.

6.1.2 It was further noted that the RCGM in its meeting held on 25.11.2008 had recommended the above proposal subject to the condition that the following information would be generated simultaneously with the trials:

- bio-efficacy data, protein digestibility, thermal stability, oral toxicity study using purified protein,
- SOPs for conducting field trials
- Validated event specific protocol of 0.01% LOD of the selected event.

6.1.3 After detailed deliberations, the GEAC approved the conduct of confined field trials (Biosafety Research Trials I) on two Bt sorghum lines containing cry 1B gene NRCSCRY1B event 4 and NRCSCRY 1B event 19 during summer (Jan 2009-May 2009) along with non transgenic lines (M35-1) and natural resistance germplasm line (IS 2205) resistant to stem borer.

6.2 Permission to conduct contained field trials (Elite Event selection trials) of 41 Bt rice lines expressing cry 1 Ab, cry 1 Ca and bar genes at their own R&D centre located at Hyderabad during Rabi-2008-09 (Dec 2008 to April 2009).

6.2.1 The Committee considered the request from M/s. Bayer Bioscience Pvt. Ltd., New Delhi to conduct elite event selection trials on 41 Bt rice lines expressing cry 1 Ab, cry 1 Ca and bar genes for research and development purpose at their own R & D farm during Rabi 2008 to April 2009).

6.2.2 It was noted that the RCGM in its 72nd meeting held on 25.11.2008 had recommended the conduct of event elite event selection trials on 41 Bt rice lines for research and development purpose at their own R & D farm subject to the following conditions:

- Submission of protein expression data generated at green house/lab conditions, biosafety data on purified protein,
- SOPs for conducting field trials
- Validated event specific protocol of 0.01% LOD of the selected event.

6.2.3 After detailed deliberations, the GEAC approved the conduct of contained field trials (Elite Event selection trials) of 41 Bt rice lines expressing cry 1 Ab, cry 1 Ca and bar genes at their own R&D centre located at Hyderabad during Rabi-2008-09 (Dec 2008 to April 2009).

6.3 Permission to conduct strip trials with transgenic tomato (*cv.* Pusa. Ruby) expressing antisense ACC synthase gene.

6.3.1 The Committee considered the request from M/s National Research Centre for Plant Biotechnology, IARI, New Delhi for conducting strip trials with transgenic tomato (*cv.* Pusa. Ruby) expressing antisense ACC synthase gene. It was noted that the proposal was approved by the GEAC in its meeting held on 1.10.2007 subject to submission of (i) name of lead scientist responsible for trials; (ii) validated event specific protocol; (iii) maintaining isolation distance of 200 m and (iv) the trial will be conducted at the IARI research farm during Rabi season (October 2007 to April, 2008).

6.3.2 The applicant has now informed that the trials could not be undertaken during the above period and has requested permission for conduct of trials during Rabi, 2009. As per the new biosafety guidelines, the applicant is also required to submit information on pure protein, heat stability, acute oral toxicity, etc. The applicant has clarified that the transgenic tomatoes developed by IARI will have no protein to inhibit ethylene biosynthesis and therefore the information on pure protein, heat stability, bio-efficacy, oral toxicity and LOD protocol is not applicable.

6.3.3 After detailed deliberations, the GEAC approved the request for conducting strip trials with transgenic tomato (*cv.* Pusa. Ruby) expressing antisense ACC synthase gene during Rabi, 2009.

Agenda Item No 7: Consideration of applications for Renewal of GEAC Permission for Commercial cultivation of Bt cotton expressing *cry 1Ac* gene (Mon-531 event) in Central and South zones.

7.1 Renewal of GEAC permission for Commercial cultivation of MRC-6025 Bt and MRC-6029 Bt cotton hybrid *expressing cry 1Ac* gene (Mon-531 event) in North zone developed by M/s. Mahyco.

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7.2 Renewal of GEAC permission for Commercial cultivation of RCH-308 & RCH-314 Bt cotton hybrid *expressing cry 1Ac* gene (Mon-531 event) in North zone developed by M/s. Rasi Seeds.

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7.3 Renewal of GEAC permission for Commercial cultivation of MRC-7347 BGII, MRC-7301 BGII and MRC-7326 BGII cotton hybrid *expressing cry 1Ac* & Cry 2 Ab genes (Mon-15985 event) in Central zone developed by M/s. Mahyco.

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7.4 Renewal of GEAC permission for Commercial cultivation of VICH 5Bt (Central and South) and VICH-9 Bt cotton hybrid *expressing cry 1Ac* gene (Mon-531 event) in Central zone developed by M/s. Vikram Seeds Ltd.

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7.5 Renewal of GEAC permission for Commercial cultivation of GK-205 and GK-204 Bt cotton hybrid *expressing cry 1Ac* gene (Mon-531 event) in Central zone developed by M/s. Ganga Kaveri Seeds Pvt. Ltd.

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7.6 Renewal of GEAC permission for Commercial cultivation of GK-207 and GK-209 Bt cotton hybrid *expressing cry 1Ac* gene (Mon-531 event) in South zone developed by M/s. Ganga Kaveri Seeds Pvt. Ltd.

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7.7 Renewal of GEAC permission for Commercial cultivation of MRC-7351 BGII and MRC-7201 BGII Bt cotton hybrid *expressing cry 1Ac* & Cry 2 Ab genes (Mon-15985 event) in South zone developed by M/s. Mahyco.

1.0 The Committee considered the requests from M/s Mahyco, M/s Rasi Seeds, M/s Ganga Kaveri Seeds and M/s Vikram Seeds Limited for renewal of GEAC permission for commercial cultivation of MRC-6025 Bt and MRC-6029 Bt, RCH-308 & RCH-314 *expressing cry 1Ac* gene (Mon-531 event) in the North Zone, MRC-7347 BGII, MRC-7301 BGII and MRC-7326 BGII *expressing cry 1Ac* and *cry 2Ab* (MON 15985 event) VICH 9 Bt, VICH 5 Bt, GK-205 and GK-204 Bt in the Central zone *expressing cry 1Ac* (MON 531 event) and VICH 5Bt, GK-207, GK-209 Bt *expressing cry 1Ac* (MON 531 event) and of MRC-7351 BGII and MRC-7201 BGII cotton hybrid *expressing cry 1Ac* & Cry 2 Ab genes (Mon-15985 event) in the South zone.

2.0 The Member Secretary, GEAC informed the Committee that the proposals at agenda items 7.1 to 7.7 were approved for commercial release in the North, Central and South zones for a period of three years subject to compliance of certain conditions in its meeting held in April/May, 2006. As the validity of GEAC approval expires in April / May, 2009, the respective Companies have submitted their applications for renewal of the GEAC permission in accordance to Rule 13 (2) of Rules 1989.

3.0 After detailed deliberations, the GEAC agreed to renew permission for commercial cultivation of Bt cotton hybrids namely MRC-6025 Bt and MRC-6029 Bt, RCH-308 & RCH-314 Bt, MRC-7347 BGII, MRC-7301 BGII and MRC-7326 BGII VICH 5Bt and VICH-9 Bt GK-205 and GK-204 Bt GK-207 and GK-209 Bt MRC-7351 BGII and MRC-7201 BGII as requested by the applicants on the following grounds:

- It was decided in the 75th GEAC meeting held on 14.3.2007 that renewal of GEAC permission after the second renewal may not be necessary as the hybrids are usually phased out after a period of four to five years with the entry of new and better hybrids / technology.

- The GEAC in its 83rd meeting held on 2.4.2008 has adopted the 'event based approval' process and the procedure for operationalizing the same has been finalized in this meeting.
- The GEAC has not received any adverse reporting on the performance of the above listed hybrids from the State Department of Agriculture / State Agricultural Universities.

Agenda Item No 8: Other Items

8.1 Discussion on the draft proposal for setting up a 'National Centre for Assessment of GMOs' prepared by Dr. P. M. Bhargava.

8.1.1 The draft proposal for setting up a 'National Centre for Assessment of GMOs (NCAG)' submitted by Dr Bhargava was considered by the Committee wherein it was noted that the proposal needs to be considered in light of new developments such as the proposed National Biotechnology Regulatory Authority (NBRA) by DBT and the Food Safety and Standards Authority (FSSA) by Ministry of Health and Family Welfare. Some members were also of the view that a separate structure/institution with hundreds of scientists and other staff in it may not be necessary at this stage taking into consideration that development and release of GMOs is extremely slow in the country. The existing institutions with adequate funding could serve the purpose. However, some members opined that a 'state of the art' institution may be necessary as a long term measure.

8.1.2 After a brief discussion on the proposal, it was decided that MoEF in the first instant may obtain comments of the concerned Ministries / Departments on Dr. Bhargava's proposal subsequent to which the next course of action would be decided.

8.2 Representation from Greenpeace regarding illegal GM food imports.

8.2.1 The Committee gave an opportunity to the representatives of M/s Greenpeace to present their views on the matter. The representatives of Greenpeace sought clarification on the action taken by the GEAC in respect of their complaint pertaining to import of Doritos Corn Chips from USA. It was clarified that the matter has been taken up with the Ministry of Commerce and Industries as well as DGFT as the import and export of restricted items are controlled at the port of entry under the DGFT Notification No 02/2006, Amendments in Schedule-I (Imports) of the ITC (HS) Classifications of Export and Import Items, 2004-09.

8.2.2 It was further clarified that neither the Ministry of Environment and Forests nor the GEAC are directly involved in the import, sale or distribution of any GM commodity including GM food products. The Rules, 1989 mandates that prior approval of GEAC is necessary before manufacture, use, import/export and storage of genetically engineering organisms or cells. Accordingly, the GEAC has informed the concerned Ministries including the Ministry of Health and Family Welfare, Ministry of Food Processing and Industries and Ministry of Commerce and Industry /DGFT that prior approval of GEAC has not been obtained in the instant matter.

The next date of the GEAC meeting is scheduled for 11.2.2009.
